Missouri Department of Health and Senior Services Recall Alert

Reese Pharmaceutical Company Announces the Voluntary Nationwide Recall of Certain Over-The-Counter Cold Relief Products that are Mislabeled.

The Missouri Department of Health and Senior Services received the following recall. The product may have been distributed in Missouri. You can identify the contaminated product by the product names and label numbers below.

ORIGINAL RELEASE-------

Contact:
Russ Slaby, Vice President
1-800-321-7178

FOR IMMEDIATE RELEASE - December 9, 2010 - Reese Pharmaceutical Company of Cleveland, Ohio has voluntarily recalled lot# 091612 only in 60-count size bottles identified under four different brand names, listed in the table below, because cold decongestant tablets (containing Acetaminophen 325 mg, Phenylephrine 5 mg & Chlorpheniramine Maleate 2 mg) were mislabeled as containing only 200mg Guaifenesin tablets. This mislabeling could cause a consumer to ingest the product and unknowingly be exposed to serious side effects of acetaminophen, phenylephrine or chlorpheniramine.

Product Name	NDC#	Lot#
Refenesen Expectorant (guaifenesin 200 mg tablets)	10956-752-60;	091612 05/11 SS/SCT36 06/26/09
Select Brand Mucus Relief Expectorant (guaifenesin 200 mg)	15127-129-60	091612 05/11 SS/SCT36 06/26/09
QC Medifin Expectorant (guaifenesin 200 mg)	63868-754-60	091612 05/11 SS/SCT36 06/26/09
Leader Cough Tabs Expectorant (guaifenesin 200 mg)	37205-466-72	091612 05/11 SS/SCT36 06/26/09

The mislabeled product does not warn consumers that Acetaminophen may cause liver damage. Ingesting high doses of Acetaminophen can potentially cause severe liver damage. The likelihood of acute liver damage is higher among consumers with pre-existing liver disease and those who drink three or more alcoholic drinks per day. Overdose may specially occur if consumers are also taking other cold/cough products that contain Acetaminophen in addition to the mislabeled product. Contraindications for Phenylephrine are high-blood pressure, poor blood flow to the extremities, and patients on antidepressants known as MAO Inhibitors. Furthermore, products that contain Phenylephrine should be used with caution in patients with high blood pressure, diabetes, heart disease, increased intraocular pressure, hyperthyroidism, or enlarged prostate. Consumers who are allergic to any of the ingredients or who have narrow angle glaucoma, or are pregnant or nursing mothers, also should not take the product. However, to date, there have been no reports of adverse events from its use.

This product was distributed nationwide. Consumers who have purchased the product (lot # 091612 only) should contact Russ or Neal Slaby at 1.800.321.7178 between 7:30-4:00pm eastern standard time for return instructions, medical information, questions, complaints or assistance.

This recall is being conducted with the knowledge of the U.S. Food and Drug Administration. Notification of the recall has been sent to all customers who purchased this product directly from Reese Pharmaceutical Company.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- **Online**:http://www.fda.gov/MedWatch/report.htm[9]
- **Regular Mail**: use postage-paid, pre-addressed Form FDA 3500 available at: http://www.fda.gov/MedWatch/getforms.htm[10]. Mail to address on the pre-addressed form.
- **Fax**: 1-800-FDA-0178